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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,370	06/22/2001	Laurie H. Glimcher	HUI-027CPDV2	8885
959	7590	02/25/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary**Application No.**

09/888,370

Applicant(s)

GLIMCHER ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-38 is/are pending in the application.
- 4a) Of the above claim(s) 27, 29-32, 34, 35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 33, 36 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 22, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>July 16, 2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional application of 09/086,010, filed May 27, 1998, now patent 6,274,338, which is a continuation in part of 09/030,579, filed February 24, 1998, now abandoned.

Applicants' amendment filed April 3, 2003, paper number 8, has been received and entered. Claims 33-38 have been added. Claims 27-38 are pending and currently under examination.

Election/Restriction

Applicant's election without traverse of group II, claims 28, 33-38, is acknowledged. In addition, the election of a species of (1) inhibiting c-Maf activity as a type of modulation; (2) the c-Maf gene as form of modulation; and (3) c-Maf nucleic acids as the type of agent used is acknowledged.

Claims 17-38 are pending. Claims 17, 29-32, 34, 35 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and spspecies, there being no allowable generic or linking claim. Election was made **without** traverse. Claims 28, 33, 36 and 38 are currently under examination as they are drawn to a method for inhibiting the human c-Maf gene in a cell by providing c-Maf nucleic acids.

Priority

It is noted that in the transmittal of the instant application, the first line of the specification was amended to indicate a claim for priority to application of 09/086,010, filed May 27, 1998, now patent 6,274,338, which is a continuation in part of 09/030,579, filed February 24, 1998, now abandoned (see transmittal letter, page 2).

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application repeats a substantial portion of prior Application No. 09/030,579, filed Feb. 24, 1998, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

This application is a Continuation-In-Part of application 09/030,579 with new matter introduced into Figures 1 and 2 (also SEQ ID NOs: 1 and 2). Applicant has inserted sequence information not previously present in the parent application. For figure 1, the applicant has insert nucleotides 515 to 720 previously represented as Ns in the parent application, and for figure 2, the applicant has inserted the corresponding new amino acids 172 to 240 previously reported as Ns. This portion of the sequence will be considered new matter, and as such will have the priority date reflected by the filing date of this application, 09/086,010 (filing date May 27, 1998).

Specification

The disclosure is objected to because of the following informalities:

First, the nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. Specifically, the drawing contain sequences that are not identified in either the drawings (see drawings 1 and 2) nor the brief description of the drawings (page 4) with specific SEQ ID NOs.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Second, in amending the priority information the appropriate information was inserted in the first line of the specification however, lines 10-13 were not indicated to be deleted

Finally, the blank space denoting the grant award (p. 1; line 6) should be filled in or the sentence should be deleted .

Appropriate correction is required.

Claim Objections

Claims 28, 33, 36 and 38 are objected to because of the following informalities:

Applicants have elected the invention drawn to a method for inhibiting the human c-Maf gene in a cell by providing c-Maf nucleic acids. Independent claim 28 should be amended to reflect the elected invention and species. In addition, if claim 28 were amended to reflect the

elected invention, claims 33, 36 and 38 would be considered non-limiting since they set forth the specific species of the elected invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

The support for newly added claims 33-38 is noted (see Applicants' amendment filed April 3, 2003, page 2). The portions of the specification pointed to by Applicants provide literal support for the general methods of modulating the activity of c-Maf gene (page 34, line 13) and methods of using inhibitory agents in general (page 34, starting at line 20). However, upon review of these portions of the specification and the remaining portions of the specification, there is no literal support for using c-Maf nucleic acids to inhibit the expression of the c-Maf gene. It is noted that the use of antisense sequences which are complimentary to c-Maf are taught, however this was set forth as a different species and not elected by Applicants. The basis of the instant rejection focuses on the fact that to practice the elected method (original claim 28), the

specific collection of species was not contemplated. In addition, beyond the teaching and literal support of the specific elected species, the specification provides no guidance to the c-Maf nucleic acid molecules that would inhibit c-Maf gene activity. There is no teaching nor evidence in the specification, nor in the art of record that c-Maf down-regulates its own expression. So even if literal support for the particular elected species is provided, the specification fails to teach how to practice the instantly claimed method.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claims 28, 33, 36 and 38 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often

necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 33, 36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The elected invention is drawn to a method for inhibiting (claim 33) the human c-Maf gene (claim 36) in a cell by providing c-Maf nucleic acids (claim 38). The claim is vague and unclear in the recitation of "c-Maf nucleic acid molecules" because what is considered a c-Maf nucleic acid is not clearly set forth in the claim nor the specification. (It is noted that c-Maf nucleic acids is in contrast to "antisense human c-Maf nucleic acid molecules" (page 34, lines 29-30) which was not elected.) More specifically, c-Maf is part of a large family of sequences encoding related proteins termed maf proteins, each sharing homology with one another. It is not clear how much of a c-Maf sequence is required or how much of the sequence is encompassed wherein any particular sequence would be considered a c-Maf sequence. As noted above, c-Maf is part of a family of proteins and it is unclear if sequences that are homologous, but from other maf family members are encompassed by the claim. Further, it is unclear if the claims encompass altered forms of c-Maf, and if so how altered a sequence could then be and still be considered a c-Maf sequence.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 28, 33, 36 and 38 are rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 6,537,810 and over claims 14-22 of U. S. Patent No. 6,537,810 .

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, because in the instant case, the elected invention encompasses expressing c-Maf in a host cell to inhibit the expression of the c-Maf gene. It is noted that neither '810 nor '671 indicate the intended consequence of inhibiting c-Maf expression by expressing c-Maf, however, by providing the expression of c-Maf nucleic acids in lymphoid cells ('810 claim 1 and '671 claim 16) the patented method claims anticipate the instant claims. Providing a possible mechanism to the specific affect on a cell for expressing

a particular nucleic acid does not differentiate the inherency of expressing said nucleic acid sequence. The allowed claims and the instantly pending claims each provide the same simple method steps for the expression of c-maf, therefore, are considered obvious over one another.

Claims 28, 33, 36 and 38 are rejected under the judicially created doctrine of double patenting over claims 10 and 11 of U. S. Patent No. 6,274,338 B1.

As reasoned above, because the elected invention encompasses expressing c-Maf in a host cell to inhibit the expression of the c-Maf gene and though the intended consequence of inhibiting c-Maf expression by expressing c-Maf is not specifically set forth in '338, by providing the expression of c-Maf nucleic acids in a host cell the patented method claims anticipate the instant claims. Again, providing a possible mechanism to the specific affect on a cell for expressing a particular nucleic acid does not differentiate the inherency of expressing said nucleic acid sequence. The allowed claims and the instantly pending claims each provide the same simple method steps for the expression of c-maf, therefore, are considered obvious over one another.

It is noted that a restriction requirement was made in '338, however the methods of expressing c-Maf in a cell were not subject to the restriction requirement.

Conclusion

No claim is allowed. The claims are free of the art of record, however they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach



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